



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

July 22, 2013

Dr. Michael Pellini, M.D.,
President, Chief Executive Officer and Director
Foundation Medicine, Inc.
One Kendall Square, Suite B3501
Cambridge, MA 02139

**Re: Foundation Medicine, Inc.
Draft Registration Statement on Form S-1
Submitted June 24, 2013
CIK No. 0001488613**

Dear Dr. Pellini:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

General

1. If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at <http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm>.
2. Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (<http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm>). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

3. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.
4. We will process your amendments without price ranges. As the price range you select will affect disclosure in several sections of the filing, we will need sufficient time to process your amendments once a price range is included and the material information now appearing blank throughout the document has been provided. Please understand that the effect of the price range on disclosure throughout the document may cause us to raise issues in areas not previously commented on.
5. Prior to the effectiveness of the company's registration statement, please inform us as to whether or not the amount of compensation allowable or payable to the Underwriters has received clearance from FINRA.
6. Prior to effectiveness, please have a NASDAQ Global Market representative call the staff to confirm that your securities have been approved for listing.
7. Please revise where and as appropriate to clarify highly specialized terms, such as epigenetics, methylation, reagents, hotspot panel tests and nucleotides.

Summary, page 1

8. We note disclosure here, pages 52 and 73 and elsewhere describing your product as the only commercially available comprehensive molecular information product designed for use in the routine care of patients with cancer. With a view to clarifying disclosure, please advise us of the extent to which these statements are subjective. For example, we note that the statements include assessments regarding "the sensitivity and specificity required for routine medical practice." In addition, they address "quality limits" and "ease of use," which also involve subjective elements. Your revised disclosure should clarify the nature of and basis for your claim to have no competitors.

The Offering, page 5

9. We note your disclosure that the number of common stock to be outstanding after this offering is based on 16,612,097 shares of your common stock outstanding as of May 31, 2013. Please supplementally provide us with a reconciliation from the 11,795,896 shares of common stock outstanding as of March 31, 2013 to the 16,612,097 shares as of May 31, 2013.

Risk Factors, page 9

10. We note the numerous references to LDT but that the acronym is not defined until page 102 as “Laboratory Developed Test.” Please revise to clarify early in your prospectus what LDT stands for.
11. The risk factor is very broad and covers topics addressed in other risk factors. Please revise to minimize repetition.

If commercial third-party payors or government payors fail to provide coverage. . . , page 22

12. Please revise in an appropriate place in your prospectus, such as page 53, to clarify the nature and expected timeline for discussions with CMS to receive a “positive national coverage decision” or other necessary approval, as appropriate. For example, it is unclear if you have had or anticipate having any appeals from decisions regarding coverage.

Use of Proceeds, page 43

13. Please revise to more specifically discuss the remainder category for your offering proceeds. For instance, it is unclear what uses comprise the “working capital” and capital expenditures” categories.
14. We note that you retain the discretion to allocate the net proceeds of the offering among the identified uses and further reserve the right to change the allocation of net proceeds among the uses described above. Please note that you may reserve the right to change the use of proceeds provided only that such reservation is due to certain contingencies that are discussed specifically and the alternatives to such use in that event are indicated. Please revise accordingly. See Instruction 7 to Item 504 of Regulation S-K.

Management’s Discussion and Analysis, page 52

15. We note on page 29 that you occasionally receive letters claiming infringement of certain intellectual property rights from third parties and invitations to take licenses under third-party patents. Please discuss these claims and invitations in terms of a known uncertainty facing your business or advise. See Item 303(a)(3)(ii) of Regulation S-K.
16. As you appear to have begun receiving revenue on your primary test product in June, 2012, please revise to clarify the nature of the products and services that generated revenues prior to that time.
17. Please revise here or where appropriate to clarify the different impact on your business between submitting claims, which you appear to do currently, and getting “coverage decisions by commercial third party payors and government payors.”

Financial Operations Overview, page 52

Revenue, page 52

18. We note your risk factor disclosure on page ten in which you state that your ability to achieve commercial market acceptance for FoundationOne is partly dependent upon your ability to obtain agreement by commercial third-party payors and governmental payors to reimburse your products, the scope and amount of which will affect patients' willingness or ability to pay for your products and likely influence physicians decisions to recommend your products. We further note your disclosure on page 53 that positive reimbursement decisions from commercial third-party payors and government payors, such as Medicare and Medicaid, would increase your overall revenue growth from ordering physicians within the United States. Please expand your overview discussion here to clearly discuss the actual effects on your financial operations for the periods presented resulting from your lack of agreement(s) with certain commercial third-party payors and government payors to reimburse your products, and from patients' willingness or ability to pay for your products. In this regard, it appears to us that these factors would have had a significant impact on your operations and liquidity for the periods presented and the known uncertainty surrounding your ability to enter into agreements with payors to obtain reimbursement for FoundationOne will continue to impact the Company in the future.
19. We note your disclosure on page 94 that you believe most patients receiving the FoundationOne test have agreed to the test knowing that they may be responsible for some portion of the cost of the test should their medical insurer deny or limit coverage. Based on your Form S-1 disclosures, it appears that you do not have agreements with certain large commercial third-party payors and government payors to reimburse your products and that the patient may ultimately be responsible for the payment of any non-covered services in certain circumstances. Please advise us of the following:
- a. Quantify for us the amount of unrecorded revenue as of December 31, 2012 and March 31, 2013 that relates to denied or limited coverage and is now due from the patient and being recorded on a cash basis.
 - b. To the extent significant, revise to quantify the amount of such unrecorded revenue, discuss your experience to-date with collecting payment from patient's for any amounts that the medical insurer has denied or limited coverage and describe the resulting impact on your operations and liquidity.
 - c. Tell us whether patients are informed of any insurance coverage denials or limits for FoundationOne prior to agreeing to the test, or if such information is not known until Foundation Medicine bills the patient's insurance company for FoundationOne. To the extent that Medicare patients are treated differently,

given that you are not currently billing Medicare patients for your tests and are not currently pursuing reimbursement from Medicare (page 94-95), please advise us of any differences related to such patients.

Results of Operations, page 55

20. We note that you qualitatively describe the primary factors that resulted in changes to your revenue and cost of revenue for each comparable period presented. Please revise to also quantify the effect of each listed factor, including separate disclosure of the effect on revenue from tests performed for biopharmaceutical customers and tests performed for ordering physicians.

Comparison of Years Ended December 31, 2011 and 2012, page 55

Revenue, page 55

21. We note your disclosure on page F-9 of revenue generated outside of the United States for each period presented. Please revise to also discuss the effect of your international operations on revenue changes between each comparable period presented, or explain to us why you believe that such disclosure is not required.
22. We note your disclosure of the number of tests performed for your biopharmaceutical customers and ordering physicians during the periods presented. We further note the disclosures throughout your Form S-1 in which you indicate that for many physician orders, you currently recognize revenue on a cash basis because the payment from the medical insurers of patients (i.e. commercial third-party payors and government payors) is not fixed or determinable and collectability is not reasonably assured. In addition, you also disclose that you do not currently have a Medicare national coverage determination for FoundationOne and, based on discussions with your Medicare contractor, you are not currently pursuing reimbursement from Medicare or billing Medicare patients. It appears to us that revenue from a large percentage of the performed tests is recognized on a cash basis. Please confirm our understanding and if so, expand your revenue disclosure to include the following information or clearly explain to us why you believe that such information is not significant enough to warrant separate disclosure under Item 303 of Regulation S-K in order to provide investors with a clear understanding of your results of operations and liquidity:
- a. Of the total tests performed for ordering physicians for each period presented, disclose the number of tests for which you have not yet recognized revenue because payment is not fixed or determinable and collectability is not reasonably assured.

- b. Disclose the average revenue per test for each period presented for your biopharmaceutical customers and ordering physicians. Also discuss the reason(s) for changes in the average revenue per test between each comparable period presented, as applicable, including a discussion of the effects on average revenue resulting from any tests performed during the period for which you did not record any revenue.
- c. To the extent that you recorded any cash basis revenue in fiscal 2013 to-date for tests that were performed in fiscal 2012, also discuss and quantify the effects on your revenue for the quarter ended March 31, 2013 resulting from such cash basis revenue recognized.
- d. Disclose the total cumulative number of tests performed for which you have not yet recognized revenue as of both December 31, 2012 and March 31, 2013.
- e. To the extent that the number of tests related to Medicare patients that you are not currently billing or pursuing reimbursement from Medicare (page 94-95) is significant, also include separate disclosure of the number of such tests performed each period and the cumulative number of tests as of both December 31, 2012 and March 31, 2013, as applicable. Also disclose whether the Company currently plans to bill patients or pursue reimbursement from Medicare for such tests in the future, or if this is dependent upon the outcome of the discussions with your Medicare contractor.

Operating Capital Requirements, page 60

23. We note your various statements in this section discussing the fact that you expect to be able to meet your planned and anticipated expenditures with funds received from ongoing operations, net proceeds from this offering and other sources of capital. Please revise to clarify your liquidity requirements on both a short-term (12 months) and long-term basis. See Instruction 5 of Item 303(a) of Regulation S-K. Also see footnote 43 in Securities Act Release No. 8350.

Application of Critical Accounting Policies, page 62

Revenue Recognition, page 63

24. Please revise to disclose whether you bill your customers for shipping and handling fees and whether you include such amounts in revenue. To the extent that you collect any taxes from customers, also disclose whether you present such taxes on a gross basis or net basis.

Business, page 73

General

25. We note the disclosure on page 94 regarding your \$5,800 list price, which appears to be paid by patients. With a view to clarifying disclosure, please advise us of the price scheme and amounts for FoundationOne depending on which entity (e.g., commercial payors) is charged.
26. Please provide the research and development disclosure required by Item 101(c)(1)(xii) of Regulation S-K.
27. We note your website indicates that the company is a Medicare provider. Please reconcile this statement with certain disclosure throughout your prospectus, such as on page 53, indicating that you do not currently have a Medicare national coverage determination for the company and are not pursuing reimbursement from Medicare patients.

Overview, page 73

28. We note your statement that your single identified genomic alteration is “associated with an FDA-approved targeted therapy or with a clinical trial, in 82% of the first 3,936 clinical specimens analyzed.” Please supplementally provide material(s) to support your assertion.
29. We note the disclosures throughout your Form S-1 in which you indicate that FoundationOne has identified at least one actionable genomic alteration in 82% of the first 3,936 clinical specimens analyzed because of its high sensitivity and specificity of interrogation of cancer-related genes for all classes of genomic alterations. Please revise to disclose the total number of clinical specimens that you have analyzed to-date, and also update the percentage of instances where at least one actionable genomic alteration was identified.
30. With a view to clarifying disclosure, please advise us of the name and importance to your business of the global biopharmaceutical partner with whom you have a multi-year engagement, referenced on page 75.

Our Industry, page 76

31. Revise to provide the citations to the referenced support for various statements under this heading so that potential investors may easily locate such materials. For instance, on page 76, you reference “a recent report by the American Cancer Society” that estimates total annual impact of premature death and disability from cancer worldwide to be approximately \$900 billion. In addition, please provide the basis for the data provided in your table on page 78.
32. Please revise page 78 to indicate what factors you considered in determining which commonly available tests to include in the table.
33. Consider defining complex industry-specific terms such as exon and intron in a footnote. See page 81.
34. Please revise pages 81 and 82 to disclose the basis for the statements regarding sensitivity and success rates.
35. Please revise to clarify whether the results of Case Study 2, on page 86, have been published and if so, please provide the citation. In addition, please provide the basis for the statements made in both Case Study 1 and Case Study 2 that, without FoundationOne, the patients would like not have received certain treatments options.

Commercialization Strategy for FoundationOne, page 88

36. Please revise to clarify what is meant by “ex-U.S.” markets on page 89.
37. We note on page 91 that you have “a number of company-sponsored and investigator-initiated clinical trials underway.” Please clarify what is meant by “investigator-initiated.”

Investing in Ongoing and new Product Innovations, page 95

38. We note the numerous references to FoundationOne for hematologic malignancies and the fact that you expect to launch this product “by early 2014.” Please revise to clarify the most significant milestones or steps before commercial launch.
39. We note, from page 73, that the FoundationOne report will be available to physicians “soon through an interactive mobile application.” Please address your mobile application under this heading or refer to the page number where the discussion appears.

Competition, page 100

40. Please revise to address the principal methods of competition (e.g., price, service, warranty or product performance). See Item 101(c)(1)(x) of Regulation S-K. In this regard, we note the \$5,800 list price on page 95.

Government Regulations, page 101

Corporate Practice of Medicine, page 107

41. Please revise to address the extent to which the identified regulations cover clinical tests that “recommend therapeutic options.” We note that your clinical test reports, as prepared by a “team of trained scientists” and computational biologist, identify therapies, FDA-approved drugs and available clinical trials “for which the patient is eligible.”

Segment and Geographical Information and Customer Concentration, page 108

42. We note your alliance with Novartis and arrangement with Illumina. Please revise to disclose the material terms of these arrangements and attach them as exhibits in

Certain Relationships and Related Party Transactions, page 127

43. We note the various consulting arrangements and your master services agreement with Agios Pharmaceuticals, Inc. Please disclose the material terms of these relationships and, in the event written agreements govern these relationships, please tell us how you considered the application of Item 601(b)(10) to these agreements.

Principal Stockholders, page 130

44. Revise to identify the natural person with voting and dispositive control over shares attributed to Laboratory Corporation of America Holdings, Gates Ventures, LLC and Wellington Management Company, LLP, or advise.

Notes to Financial Statements, page F-7

10. Significant Agreements, page F-27

45. We note your disclosure that you assessed your MSA with a Biopharmaceutical Customer as a multiple-element arrangement pursuant to ASC 605-25, and determined that the deliverables were not separable due to a lack of stand-alone value for certain delivered items. Please provide us with your analysis of each identified deliverable to determine whether it has value to the customer on a standalone basis. For each deliverable, also include the factors that support or do not support a determination that

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the deliverable has value to the customer on a standalone basis, and explain the judgment used to reach your final conclusion.

Part II

Information Not Required in Prospectus, page II-1

Undertakings, page II-4

46. We note your disclosure of the Commission's position on indemnification for Securities Act Liabilities in accordance with Item 510 of Regulation S-K. Please revise to locate such position in your prospectus, as required by Item 12A of Part I of Form S-1, or incorporate the statement by reference into your prospectus.

Exhibits, page II-7

47. We note that you have not filed your exhibits, including the underwriting agreement and your legality opinion. Please note that we may comment on these and other documents and allow for sufficient time for our review.
48. We note that Exhibit 10.11 is missing schedules, exhibits or attachments. Please file this exhibit in its entirety as required by Item 601(b)(10) of Regulation S-K.

You may contact Myra Moosariparambil at (202) 551-3796 or John Archfield at (202) 551-3315 if you have questions regarding comments on the financial statements and related matters. Please contact Erin Wilson at (202) 551-6047 or James Lopez at (202) 551-3536 with any other questions.

Sincerely,

/s/ James Lopez (for)

John Reynolds
Assistant Director